

MAY 30 2001

510(k) Summary of Safety and Effectiveness  
ArthroCare, Corporation

K010811

**General Information**

**Manufacturer:**

ArthroCare, Corporation  
595 North Pastoria Avenue  
Sunnyvale, CA 94085-2936

**Establishment Registration Number:** 2951580

**Contact Person:**

Bruce Prothro  
Vice President Regulatory Affairs, Quality  
Assurance, and Clinical Research

**Date Prepared:**

**Device Description**

**Classification Name:**

Electrosurgical Cutting and Coagulation  
Device and Accessories (21 CFR 878.4400)

**Trade Name:**

Perc-D™ SpineWand™

**Generic/Common Name:**

Electrosurgical Device and Accessories

**Predicate Devices**

- |   |         |
|---|---------|
| • ArthroCare Orthopedic Electrosurgery System (System 2000)   | K992581 |
| • Oratec SpineCATH Intradiscal Catheters  | K993967 |
| • Coherent VersaPulse Select Single Wavelength (Ho:YAG) Dual<br>Wavelength (Ho:YAG/Nd:YAG) Laser System | K990947 |

**Intended Use**

The Perc-D SpineWand is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.

**Product Description**

The Perc-D SpineWand is a single use, disposable bipolar electrosurgical device designed to be used in conjunction with the ArthroCare System 2000.

**Substantial Equivalence**

In establishing substantial equivalence to the predicate devices, ArthroCare evaluated the indications for use, materials, technology, product specifications, and energy requirements of those systems. Additionally, performance testing has been completed to demonstrate the substantial equivalence of the Perc-D SpineWand to the predicate devices. The performance testing and device comparison demonstrated that the subject devices are substantially equivalent to the predicate devices, and are safe and effective for their intended use.



MAY 3 0 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Bruce Prothro  
Vice President Regulatory Affairs,  
Quality Assurance, and Clinical Research  
ArthroCare Corporation  
595 North Pastoria Avenue  
Sunnyvale, California 94085

Re: K010811  
Trade/Device Name: Perc-D™ Spine Wand™  
Regulation Number: 878.4400  
888.1100  
Regulatory Class: II  
Product Code: GEI, HRX  
Dated: March 16, 2001  
Received: March 19, 2001

Dear Mr. Prothro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

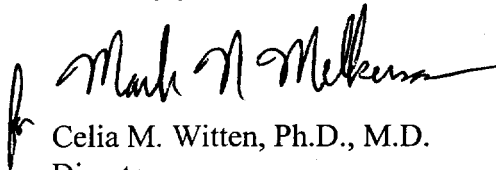
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Bruce Prothro

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications Statement

Device Name: Perc-D™ SpineWand™  
510(k) Number: ~~K00~~ K010811

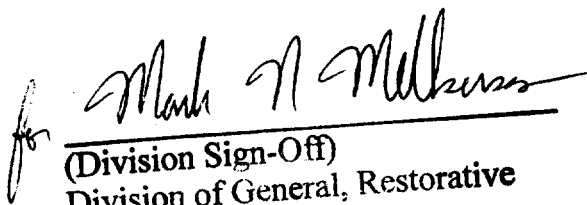
Indications for use:

The Perc-D™ SpineWand™ is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X   OR Over-the-Counter Use             
(Per 21 CFR 801.109)



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number           K010811